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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,089	SAKAKIBARA ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-9,18,22-36,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31-34 and 36* is/are allowed.

6)☒ Claim(s) *1,5-9,18,22-30,35,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is written in response to the papers received 7/27/04. Claims 1, 5, 18, 22, 33, 34 have been amended and claims 27-43 have been canceled, and claims 44-45 have been added. Claims 1, 5-9, 18, 22-36 and 44-45 are pending and examined herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The status of all of the rejections is addressed in this office action, and applicant's remarks are addressed in the section of this office action headed "Response to Remarks." The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is final.**

Sequence Rules

2. This application is in compliance with the sequence rules.

Specification

3. The objection to the specification is withdrawn in view of the new sequence listing provided 7/27/04.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 5-9, 18, 22, 23, 24, 25, 26, 37, 38, 39, 40, 41, 42, and 43 under 35 U.S.C. 112, first paragraph, as containing new matter is WITHDRAWN in view of the amendment or cancellation of the rejected claims.

5. The rejection of claims 37, 39, 41, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention is WITHDRAWN in view of the cancellation of these claims.

6. Claims 1, 5-9, 18, 22-26, 27-30, 35, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a protein having activity to synthesize aureusidin by using chalcones as substrates, wherein the nucleic acid comprises a sequence encoding SEQ ID NO: 2, does not reasonably provide enablement for any other nucleic acids encoding such proteins, or for nucleic acids encoding proteins that have the ability to synthesize any other aurones. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claim 1 encompasses an isolated gene which encodes a protein having activity to synthesize aurones using chalcones as substrates, wherein said gene is obtained from *Antirrhinum*. Claim 5 depends from claim 1 and recites that the claimed gene encodes an amino acid sequence having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2 and encodes a protein having activity to synthesize aurones using chalcones as substrates. Claims 6-9 recite vectors and host cells. Thus, the scope of claim 1 and the claims which depend from claim 1 encompass nucleic acids from any plant within the genus *Antirrhinum*. There is a single species within this genus, *A. majus*. Furthermore, claim 1 recites an isolated "gene" which encompasses genomic DNAs that include untranslated regions such as promoters and introns and 3' regulatory regions.

Claim 18 is drawn to an isolated nucleic acid encoding a protein having activity to synthesize aurones by preferentially using chalcones as substrates, wherein said gene is obtained from *Antirrhinum*. Claim 22 depends from claim 18 recites that the claimed gene encodes an amino acid sequence having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2 and encodes a protein having activity to synthesize aurones using chalcones as substrates. Claims 23-26 recite vectors and host cells. Thus, the scope of claim 18 and the claims which depend from claim 18 encompass nucleic acids from any plant within the family *Antirrhinum*.

Claim 27 is drawn to an isolated nucleic acid obtained from *Antirrhinum majus* encoding a protein having an activity to synthesize aurones using chalcones as substrates. Claims 28-30 depend from claim 27 and recite vectors and host cells.

Claim 35 is drawn to an isolated gene encoding a protein having activity to synthesize aurones using chalcones as substrates, wherein said protein has the amino acid sequence of SEQ ID NO: 2. Claim 35 recites an isolated "gene" which encompasses genomic DNAs that include untranslated regions such as promoters and introns and 3' regulatory regions.

Newly added claim 44 recites an isolated gene having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2, and encoding a protein having activity to synthesize aurones using chalcones as substrates. Claim 44 recites an isolated "gene" which encompasses genomic DNAs that include untranslated regions such as promoters and introns and 3' regulatory regions. Further, the claim encompasses molecules with changes relative to SEQ ID NO: 2 allowed by the homology language. Further it is noted that the language of this claim recites an ability to synthesize any aurone, and as discussed in this

rejection, the specification only demonstrates the ability of SEQ ID NO: 2 to synthesize aureusidin.

Newly added claim 45 an isolated nucleic acid having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2, and encoding a protein having activity to synthesize aurones using chalcones as substrates. Like claim 45, the claim encompasses molecules with changes relative to SEQ ID NO: 2 allowed by the homology language. Further it is noted that the language of this claim recites an ability to synthesize any aurone, and as discussed in this rejection, the specification only demonstrates the ability of SEQ ID NO: 2 to synthesize aureusidin.

Furthermore, it is noted that claims 7, 8, 24, and 25 include the recitation of a "host cell" which encompasses whole organisms such as transgenic animals for which no disclosure or support is provided (see specification page 9). To make and use such animals would require undue experimentation as it is entirely unknown how the expression of the instantly disclosed nucleic acids would effect such animals. The amendment of these claims to clarify that the "host cells" are isolated would overcome this concern.

The specification teaches a single cDNA molecule (SEQ ID NO: 1) which encodes the polypeptide SEQ ID NO: 2. The working examples demonstrate that the polypeptide encoded by SEQ ID NO: 1 has the ability to synthesize aureusidin by using chalcones as substrates (Examples 3 and 6). The specification further teaches that the enzyme tyrosinase form the organisms Neurospora also has the ability to synthesize aureusidin by using chalcones as substrates (Example 18). The nucleic acid encoding the Neurospora tyrosinase was known in the prior art at the time the invention was made (see Kupper *et al.*), but does not fall within the

scope of the instantly rejected claims because it is not isolated from one of the recited organisms. The specification also teaches that instant SEQ ID NO: 2 has a copper binding region that is typical of the active center of polyphenol oxidases (Example 10).

The specification at page 5 generically discusses that enzymes have regions that are essential and non-essential for enzyme activity, but the specification does not provide examples of any of these regions for instant SEQ ID NO: 2. Further, the specification provides fragments of SEQ ID NO: 2 that were sequenced prior to the isolation of the full length SEQ ID NO: 1 from which SEQ ID NO: 2 was deduced. These fragments are SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, and SEQ ID NO: 6 as disclosed in the specification (as opposed to within the sequence listing). The specification within example 9 teaches the isolation of a nucleic acid encoding a partial enzyme, that is SEQ ID NO: 7 via subtractive hybridization. The specification does not provide a full length cDNA that encodes SEQ ID NO: 7. The specification does not demonstrate that any of these fragments is sufficient to confer on an enzyme the ability to synthesize aureusidin using chalcones as substrates.

The specification and the prior art are silent as to any other polypeptides that have the ability to synthesize aureusidin by using chalcones as substrates, or any polypeptides that have the ability to synthesize any other aurones (other than aureusidin) from chalcones. The specification does not provide any guidance as to what portions or fragments of instant SEQ ID NO: 2 are necessary to retain this activity. Neither the specification nor the prior art establish any relationship between all polypehnol oxidases and the activity that is attributed to instant SEQ ID NO: 2 and the Neurospora tyrosinase.

There are many polyphenol oxidase molecules (and nucleic acids encoding them) known in the prior art (see, for example, Hunt *et al.*, cited in paper number 30, Boss *et al.* and Robinson *et al.*). However, neither the specification nor the prior art provide any guidance that would lead any person skilled in the art to select of all of the possibilities which nucleic acids already discovered, or yet to be discovered, would possess the ability to synthesize aureusidin by using chalcones as substrates, or the ability to synthesize any other aurone using chalcones as substrates. Particularly, the neither the specification nor the prior art provide any guidance as to which nucleic acids encoding polyphenol oxidase enzymes encode those that use chalcones as substrates. In fact the only common structural feature that the specification has suggested that instant SEQ ID NO: 2 has with polyphenol oxidases is the fact that it has a copper binding region.

While the level of skill in the relevant art is quite high (PhD in biochemistry), the level of unpredictability is higher with regard to the ability to change an amino acids in a particular sequence while still retaining the functionality of the enzyme. The specification provides absolutely no guidance as to which or how many of the amino acids of instant SEQ ID NO: 2 can be changed yet still result in a polypeptide which retains the ability to synthesize aureusidin by using chalcones as substrates. Further, the specification gives no guidance as to the structure or identity of nucleic acids encoding any other sequence that has the ability to synthesize aurones other than aureusidin.

The identification of other nucleic acids that fall within the scope of the instantly claimed invention would require the screening of every possible enzyme isolated from the recited organisms to determine if they have the recited functionality. Such a search would be

complicated by the fact that the skilled artisan would have no guidance as to which enzymes which are known or unknown would fall within the scope of the claimed invention.

Because of the breadth of the claims, the provision of only one sequence within the scope of the claims that has the ability to synthesize aureusidin by using chalcones as substrates, and only a single amino acid sequence isolated from *Antirrhinum*, the lack of any showing that other aurones could be synthesized, the fact that full length genes (i.e. genomic sequences) are not provided which encode polypeptides shown to have the ability to synthesize aureusidin by using chalcones as substrates, the lack of direction in the specification of the identity and structure of other such enzymes, and the large quantity of experimentation necessary to identify other members of the claimed group, it is concluded that undue experimentation would be necessary to practice the claimed invention commensurate in scope with the instantly rejected claims.

7. Claims 1, 5-9, 18, 21-26, 27-30, 35, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim 1 encompasses an isolated gene which encodes a protein having activity to synthesize aurones using chalcones as substrates, wherein said gene is obtained from *Scrophulariales*. Claims 5 each depends from claim 1 and recites that the claimed gene encodes an amino acid sequence having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2 and encodes a protein having activity to synthesize aurones using chalcones as substrates. Claims 6-9 recite vectors and host cells. Thus, the scope of claim 1 and

the claims which depend from claim 1 encompass nucleic acids from any plant within the family *Antirrhinum.*. Furthermore, claim 1 recites an isolated "gene" which encompasses genomic DNAs that include untranslated regions such as promoters and introns and 3' regulatory regions.

Claim 18 is drawn to an isolated nucleic acid encoding a protein having activity to synthesize aurones by preferentially using chalcones as substrates, wherein said gene is obtained from *Antirrhinum*. Claim 22 each depends from claim 18 recites that the claimed gene encodes an amino acid sequence having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2 and encodes a protein having activity to synthesize aurones using chalcones as substrates. Claims 23-26 recite vectors and host cells. Thus, the scope of claim 1 and the claims which depend from claim 1 encompass nucleic acids from any plant within the family *Antirrhinum*.

Claim 27 is drawn to an isolated nucleic acid obtained from Antirrhinum majus encoding a protein having an activity to synthesize aurones using chalcones as substrates. Claims 28-30 depend from claim 27 and recite vectors and host cells.

Claim 35 is drawn to an isolated gene encoding a protein having activity to synthesize aurones using chalcones as substrates, wherein said protein has the amino acid sequence of SEQ ID NO: 2. Claim 35 recites an isolated "gene" which encompasses genomic DNAs that include untranslated regions such as promoters and introns and 3' regulatory regions.

Newly added claim 44 recites an isolated gene having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2, and encoding a protein having activity to synthesize aurones using chalcones as substrates. Claim 44 recites an isolated "gene" which encompasses genomic DNAs that include untranslated regions such as promoters and

introns and 3' regulatory regions. Further, the claim encompasses molecules with changes relative to SEQ ID NO: 2 allowed by the homology language. Further it is noted that the language of this claim recites an ability to synthesize any aurone, and as discussed in this rejection, the specification only demonstrates the ability of SEQ ID NO: 2 to synthesize aureusidin.

Newly added claim 45 an isolated nucleic acid having a homology of at least 95% relative to the amino acid sequence described in SEQ ID NO: 2, and encoding a protein having activity to synthesize aurones using chalcones as substrates. Like claim 45, the claim encompasses molecules with changes relative to SEQ ID NO: 2 allowed by the homology language. Further it is noted that the language of this claim recites an ability to synthesize any aurone, and as discussed in this rejection, the specification only demonstrates the ability of SEQ ID NO: 2 to synthesize aureusidin.

Claims 1 and 18 are so broad as to encompass nucleic acids encoding any possible enzyme that has the recited activity, provided the enzyme was isolated from a plant within the genus *Antirrhinum*. Claim 27 is so broad as to encompass nucleic acids encoding any possible enzyme that has the recited activity, provided the enzyme was isolated from Antirrhinum majus. This genus has a single known species, that is A. majus, but claims 1 and 18 are sufficiently broad so as to encompass genes and nucleic acids from any species of plant which may be considered within this genus in the future. Further, the claims encompass any nucleic acid encoding any polypeptide that has the function to synthesize aurones using chalcones as substrates isolated from *Antirrhinum.* Claim 1 differs from claims 19 and 27 in the recitation of a "gene" clearly speaks to full length genomic nucleic acids. The claims provide no structure to

define the claimed nucleic acid. Neither the specification nor the claims provide any description as to what characteristics of a polypeptide would identify it or classify it as being "obtained" from within this genus of plants. That is, of all of the possible enzymes that have activity to synthesize aurones using chalcones, the specification does not provide any description as to how to identify the ones that are obtained from *Antirrhinum*.

Claims 5, 22, 44, and 45 all recite that the claimed gene or nucleic acid encode a polypeptide that has 95% identity to instant SEQ ID NO: 2. However, the specification has not described where or how instant SEQ ID NO: 2 can be modified yet still retain the functionality required by the instant claims. There is no teaching in the specification as to how the recited function is correlative with any structure.

Of all of the potential nucleic acid sequences encompassed by the rejected claims, only a single example is provided in the specification, that is, the nucleic acid encoding SEQ ID NO: 2. Thus, applicant is in possession of nucleic acids encoding only a single amino acid sequence, that is SEQ ID NO: 2. Claims 1, 35, and 44 are also drawn to genes, and encompass, therefore, genomic coding sequences. Such a sequence includes 5' and 3' untranslated regions, introns, and other regulatory sequences. However, applicant has only described the coding portion of the nucleic acid encoding SEQ ID NO: 2.

As noted in the scope of enablement rejection, the specification does not teach a nucleic acid that has the ability to synthesize any aurone except aureusidin. With regard to the functional requirement of the claims, applicant is in possession only of nucleic acids encoding SEQ ID NO: 2 which has the activity to synthesize aureusidin from chalcones.

Thus, applicant has express possession of only one species in a genus which comprises hundreds of millions of different possibilities.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 5, 22, 44, and 45 include modifications by permitted by the % identity language for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only nucleic acids encoding instant SEQ ID NO: 2 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids that encode proteins modified by addition, insertion, deletion, substitution or inversion with respect to the disclosed SEQ ID No: 2 such that a different amino acid sequence is encoded which has the activity to synthesize aureusidin (or any other aurone) from chalcones.

Response to Remarks

112 1st, Scope of enablement

The scope of enablement rejection is maintained and applied to newly added claims 44 and 45.

Applicant argues that using the guidance provided in the specification one skilled in the art could readily obtain other sequences which encode a protein having activity to synthesize aurones as instantly claimed (arguments ¶ bridging p. 9-10 of response). However, this does not address the fact that applicant has not taught one skilled in the art how to make and use the invention. Screening for molecules which may fall into the scope of the broad claims is not a teaching of how to make a particular nucleic acid. As previously noted, there is a high degree of unpredictability as to how instant SEQ ID NO: 2 can be modified yet still retain its function as being able to synthesize aureusidin, or can be modified so as to be able to synthesize a different aurone. The class of pigments know as "aurones" encompasses a number of pigments in addition to aureusidin, including at least 4',6-dihydroxyaurone, 4, 4',5-trihydroxyaurone, sulfretin and bracteatin. Applicant has not provided any guidance as to nucleic acids which encode enzymes that synthesize any of these pigments. In fact, the specification clearly states that aurones produced by the newly discovered enzyme are "not 4',6-dihydroxyaurone considered in the prior art, but rather aureusidin (specification p. 2, lines 30-35)."

The specification does not provide any guidance in this regard, indeed the specification only teaches a single molecule that has the ability to synthesize aureusidin from chalcones. A teaching of a general screening method cannot overcome the lack of additional guidance in light of the high level of unpredictability in the related technology.

Applicant suggests that one skilled in the art would be able to practice the invention as claimed based upon the teachings of the specification using SEQ ID NO: 1 as a probe to obtain other sequence which could encode a protein having activity to synthesize aurones as instantly claimed. However, this is not persuasive, because it is highly unpredictable, of all of the nucleic acids that would hybridize with instant SEQ ID NO: 1, which ones would have the ability to synthesize aurones by preferentially using chalcones as substrates. There is a complete lack of guidance in the specification as to how to select polynucleotides that encode enzymes having the ability to synthesize any aurone besides aureusidin. The specification provides no guidance as to how SEQ ID NO: 2 can be modified while still arriving at a polypeptide with the recited activity. All of these are highly unpredictable areas, and absent further guidance the ordinary practitioner would not be able to practice the claimed invention commensurate in scope with the claims.

The rejection is MAINTAINED.

112 1st, Written description

The written description rejection is maintained and applied to the newly added claims 44 and 45.

Applicant points to pending claims 1 and 18 and states that the claims are specifically directed towards an isolated gene or nucleic acid encoding a protein having activity to synthesize aurones using chalcones as substrates, wherein the gene is obtained from *Antirrhinum*. As discussed in the rejection, these claims provide no structure for the claimed nucleic acids. Claim 1 specifically recites a "gene" when no genomic sequences has been described. Neither the claims nor the specification provides description as to how to identify a particular nucleic acid as being from *Antirrhinum*. And finally, only a nucleic acid encoding a single polypeptide has been

described and the encoded enzyme only catalyzes the production aureusidin, not any possible aurone. The functional recitation in the claims is not commensurate in scope with the showing of the functional ability of the enzyme encoded by the disclosed polynucleotide. That is, the term "aurone" encompasses a number of pigments in addition to aureusidin, including 4',6-dihydroxyaurone, 4, 4',5-trihydroxyaurone, sulfretin and bracteatin. Applicant has not demonstrated possession of nucleic acids which encode enzymes that can synthesize any of these.

In the first paragraph of page 11, applicant points out that the specification refers to the disclosed cDNA as a "gene" on page 3 of the specification. Nonetheless, the specific use of the identifier "gene" encompasses full length genomic sequences which were not described in the specification. Applicant further argues that one would know how to obtain the full length sequence using the sequences identified in the specification. However, this is not persuasive, because the issue is not COULD one obtain additional sequences, but instead, the issue is whether or not applicant had possession of the claimed invention at the time the invention was made or whether applicant adequately described the claimed invention to demonstrate such possession. The court has stated, "While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not." In Re Ruschig, 379 F.2d 990, 995, 154 U.S.P.Q. 118, 123 (CCPA 1967). Further, the court has stated "Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." The Regents of the University of California v.

Eli Lilly & Co., 43 U.S.P.Q.2d 1406 (Federal Circuit 1997). In the instant case, it is not even clear that given the teachings of the specification one of skill in the art could in fact make the claimed invention, as discussed in the enablement rejection. In either instance, the claimed invention does not meet the written description requirement for all of the reasons discussed herein.

The rejection is MAINTAINED.

Conclusion

8. Claims 31, 32, 33, 34 and 36 are allowed. The prior art does not teach or suggest an isolated nucleic acid encoding an amino acid sequence as shown in SEQ ID NO: 2, or an isolated nucleic acid sequence having the nucleotide sequence of SEQ ID NO: 1, nor does the prior art teach or suggest the recited constructs which comprise these sequences.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Juliet C. Switzer
Examiner
Art Unit 1634

September 24, 2004